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09/114,973	07/14/1998	WILLIAM F. DOVE	960296.95491	9862

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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 06/19/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/114,973

Applicant(s)

DOVE ET AL.

Examiner

Joseph Voitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Application/Control Number: 09/114,973

Page 2

Art Unit: 1632

***Continued Prosecution Application***

The request filed on April 8, 2002, paper number 25, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/114,973 is acceptable and a CPA has been established. An action on the CPA follows.

**DETAILED ACTION**

This application filed July 14, 1998, is a continuation in part of application 08/751,292, filed November 18, 1996, now patent 5,780,236.

Applicant's amendment filed April 8, 2002, paper number 26, has been received and entered. Claims 27 and 28 have been amended. Claims 30-42 have been added. Claims 1-42 are pending.

***Election/Restriction***

Applicants note that arguments to the previous traversal appear incomplete, and request that comments regarding the restriction requirement be included in the subsequent office action.

Claims 10-25 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16. Applicant's traversal was fully considered and not found persuasive in the previous office action,

Art Unit: 1632

paper number 18 (see arguments on page 2). The restriction was found proper and the requirement was made FINAL. Applicant's new grounds of traverse in Paper No. 20 was acknowledged. The traversal was on the ground(s) that Group I and II should be rejoined because if group II, claim 10, were elected, a proper search for art would necessarily search for art relating to method steps recited in group I. In addition, Applicant argues that it would be an substantial burden to pay additional filing fees and prosecution costs. See Applicants' previous amendment (paper number 20), bridging paragraph on pages 5-6. Applicant's arguments have been fully considered and found persuasive.

Upon review of the present disclosure and consideration of Applicants' arguments, Examiner agrees that the methods encompassed by claims 10-25 would necessarily include the search required for the methods encompassed by Group I. Further, given that animals are often used as models for conditions and diseases found in humans, upon the identification of a particular mutation/gene in an animal model, routinely one of skill in the art would use this information to identify and confirm the presence and association of similar mutation/gene in humans. Examiner would agree that the methods encompassed by claims 10-25 would be obvious extensions of the methods presently elected. Therefore, the restriction requirement is withdrawn.

Claims 1-42 are pending and currently under examination.

Art Unit: 1632

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of isogeneic/index mice with defined murine genetic locus, does not reasonably provide enablement for any and all non-human animals is withdrawn.

Applicants note that inbred strains of mice, rats and rabbits are already commercially available. Further, given the level of skill in the art of genetics any animal system exhibiting Mendelian inheritance could be successfully bred using methods known in the art to provide other inbred animals. In view of the presence of inbred strains of several mammals, and the ability of one of skill in the art to generate inbred lines of other animals, Applicants argue that the mere absence of all the inbred lines encompassed by the instant claims should not constitute undue experimentation. See Applicants' amendment, pages 9-11. Applicants arguments have been fully considered and found persuasive.

Upon review of the present disclosure, the art of record and consideration of Applicants arguments, Examiner agrees that the present invention would not require undue experimentation to practice. Specifically, the method steps recited in the claims require methodology which is routine in the art. Further, Examiner would agree that though many of the species encompassed by the instant claims are not present as inbred lines, given the level of skill in the art, one could

Art Unit: 1632

identify animals which exhibit the desired phenotypes and using standard methodology known in the art, generate inbred lines for use in the instantly claimed methods.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 1, 2, 26, 30, 31 and 39 are unclear and confusing in the recitation of crossing 'gametes'. The specification does not specifically define this term, however the art recognizes this term to mean and encompass a germ cell, either ovum or spermatozoon. The breeding of animals usually encompasses mating of individuals, and it is unclear if the claims are directed to only producing a N2 generation by *in vitro* fertilization. More clearly indicating how the breeding/crosses are accomplished would obviate the basis of the rejection.

Claims 1, 26 and 30 are vague and unclear in the recitation of 'the F1 progeny that carry the dominant allele also carry at least one random mutation' because it is not clear how this is determined within the given method steps. The method is directed to finding a single point mutation, and so it is unclear how the artisan determines the presence or absence of the mutation before its actual determination.

Art Unit: 1632

Claims 3 and 32 are vague and indefinite in the recitation of 'extreme outlying phenotype' because the metes and bounds of what is encompassed by 'extreme' is not defined. It is unclear what this term encompasses or how a phenotype is determined to be 'extreme' within the method steps instantly recited.

Claim 4 is unclear in the recitation of a segregating mutation which 'is a heterozygous modifier' because it is unclear how a single mutation can at the same time both enhance and suppress an observed phenotype/activity.

Claims 6 and 35 are unclear and confusing in the recitation of 'share an isogenic background' because both the strains are clearly genetically different. Isogenic is recognized in the art to mean genetically identical, and so it is unclear how two genetically unrelated strains would be considered isogenic. The metes and bounds of the claim are unclear and indefinite because even if some of the genetic background was similar, i.e. strains derived from common parents, it is unclear how related the strains must be to meet the limitation of the claims.

Claim 7 is incomplete because it is directed to 'mapping the segregating mutation' however the method steps only result in sib-mating of progeny.

Claim 8 is unclear and confusing in the recitation of 'a wild-type inbred mouse' because a wild-type mouse is not usually inbred (*i.e.* usually outbred). Amending the claim to reflect the nature of what is encompassed by 'wild-type' would obviate the basis of the rejection.

Art Unit: 1632

Claim 26 is incomplete because the final step of the method does not result in the identification of a segregating mutation. Clearly indicating that the mutation is identified/characterized would obviate the basis of the rejection.

Claims 27 and 40 are unclear because the antecedent basis for 'the probability', 'the denominator', 'the numerator', 'the method of maximum likelihood' and 'the potential carriers' lack antecedent basis in claim 27, and claims 26, 6 and 1. More clearly setting forth the equations used in the method of evaluation would obviate the basis of the rejection.

Claim 28 is unclear and confusing in the recitation of 'having the genetic background of the index strain' because 'the genetic background' lacks antecedent basis in the claim and it is unclear what the genetic background of the strain should be.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-25 rejected under 35 U.S.C. 102(a) as being anticipated by Bilger *et al.* is withdrawn.

Applicants argue that the animals crossed by Bilger do not meet the limitations set forth in claim 1, and that the differences in those mice result in substantially different products.



Art Unit: 1632

Specifically, claim 6 recites that the strains share an isogenic genetic background. Claim 8 recites that the fonder strain carry a random point mutation, and that claim 9 requires a particular mutagen (specifically ethylnitrourea-ENS). See Applicants' amendment, pages 8-9. Applicants amendment has been fully considered, but not found persuasive.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Bilger *et al.* and Rinchik *et al.* is withdrawn.

Claim 27 rejected under 35 U.S.C. 103(a) as being unpatentable over Bilger *et al.* and Dietrich *et al.* is withdrawn.

Art Unit: 1632

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Gould, K. *et al.* Genetics 132:1777-1785, 1996. Gould *et al.* teach a method for the genetic mapping of quantitative trait loci (QTL) and use a mouse model comprising the gene specifically set forth in the present claims. Though inbred lines are bred to identify loci of interest (see Table 2, page 1782), the Rec lines encompass more than single point mutations. In the analysis of the resulting phenotype of particular crosses, Gould *et al.* conclude that the *Mom1* locus is complex, clearly indicating that more than a single point mutation or single gene is responsible for the observed phenotype (page 1784, middle of first column).

Lande, R. *et al.* Genetics 124:734-756, 1990. Lande *et al.* teach methods of mapping marker loci and provide evidence that for the successful use of QTL full and half sib relationships are preferred, otherwise large populations are necessary to accurately map a QTL.

Hillel, J. *et al.* Genetics 124:783-789, 1990, and Hopital, F. *et al.* Genetics 132:1199-1210, 1992. Each teach breeding programs and the use of different markers to study gene introgression. Hillel *et al.* teach that genome similarity can be accomplished with recurrent back-crossing, and results in a sample with a low variance in genomic selection. The use of DNA fingerprinting is used to demonstrate relevant differences of breeding schemes. Hopital *et al.* provides further teachings and evidence for the number of back-crosses necessary for the study of introgressed genes of interest.

Art Unit: 1632

Each reference provides evidence for the level of skill in the art and the use of cross-breeding for the analysis of a loci. However, in view of the complexity of locus responsible for a QTL, the art of record does not suggest the use of such methodology for the identification of a single point mutation.

***Conclusion***

No claim is allowed. Claims 1-42 are free of the art of record, however the claims are subject to other rejections or dependent on rejected claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

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